



EU Declaration of Conformity

Manufacturer:

Unimed Medical Supplies, Inc

SRN: CN-MF-000001480

Address:

Bld#8, Nangang 3rd Industrial Park, Tangtou,
Shiyan, 518108, Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Obelis s.a.

SRN: BE-AR-000000106

Address:

Boulevard Général Wahis 53
1030 Brussels, BELGIUM

Device Name: ECG Cables & Lead Wires

Trade Name: Refer to attachment *List of Devices*

Device Model: Refer to attachment *List of Devices*

GMDN Code: 35562

CND Code: Z12050385

Basic UDI-DI: 69456648REC1YF

Classification: I (According to Rule 1 of Annex VIII of Regulation (EU) 2017/745)

We hereby declare under our sole responsibility that the above mentioned device(s) comply(ies) with the provisions of the Regulation (EU) 2017/745 on Medical Device.

Conformity Assessment Procedure: Annex II and III of Regulation(EU)2017/745

Standards and CS Applied: Refer to attachment *List of Applied Standards and CS*

We hereby also declare under our sole that the product(s) listed in Annex comply(ies) with the provisions of Directive 2011/65/EU.

The CE Mark:



Shenzhen, December 17, 2021

Place, Date of Issue

General Manager, FrankZhang

Position, Name, Signature

Attachment of EU Declaration of Conformity: List of Devices

List of Devices

Device Model	Device Trade Name and General Description
GEK10-AD-I	GE KISS 10-lead complete set cable,1.47M(F.L.R.N)+1.27M(C1-C6)
X-GEK-127SC-C1	GE KISS cable, single lead C1(red),1.27M,IEC
X-GEK-127SC-C2	GE KISS cable, single lead C2(yellow),1.27M,IEC
X-GEK-127SC-C3	GE KISS cable, single lead C3(green),1.27M,IEC
X-GEK-127SC-C4	GE KISS cable, single lead C4(brown),1.27M,IEC
X-GEK-127SC-C5	GE KISS cable, single lead C5(black),1.27M,IEC
X-GEK-127SC-C6	GE KISS cable, single lead C6(purple),1.27M,IEC
X-GEK-147SC-F	GE KISS cable, single lead F(green),1.47M,IEC
X-GEK-147SC-L	GE KISS cable, single lead L(yellow),1.47M,IEC
X-GEK-147SC-R	GE KISS cable, single lead R(red),1.47M,IEC
X-GEK-147SC-N	GE KISS cable, single lead N(black),1.47M,IEC
Y05-T286	GE KISS suction electrodes, single piece
Y05-T286-10	GE KISS suction electrodes, 10 pieces/pack
Y05-T283-100	GE KISS suction electrodes filter pads, white, 100pcs/pack

Attachment of EU Declaration of Conformity: List of Applied Standards and CS

List of Applied Standards and CS

EN ISO 15223-1:2021	Medical device – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturers
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Sensitization
EN ISO 14971:2019	Medical devices-Application of risk management to medical devices
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
AAMI ANSI EC53:2013	ECG Trunk Cables and Patient Leadwires